PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/02, 17/36

A1

(11) International Publication Number: WO 97/17014

(43) International Publication Date: 15 May 1997 (15.05.97)

(21) International Application Number: PCT/NO96/00263

(22) International Filing Date: 8 November 1996 (08.11.96)

(30) Priority Data:
954552 10 November 1995 (10.11.95) NO

(71) Applicant (*for all designated States except US*): NYFOTEK AS [NO/NO]; Strindveien 4, N-7034 Trondheim (NO).

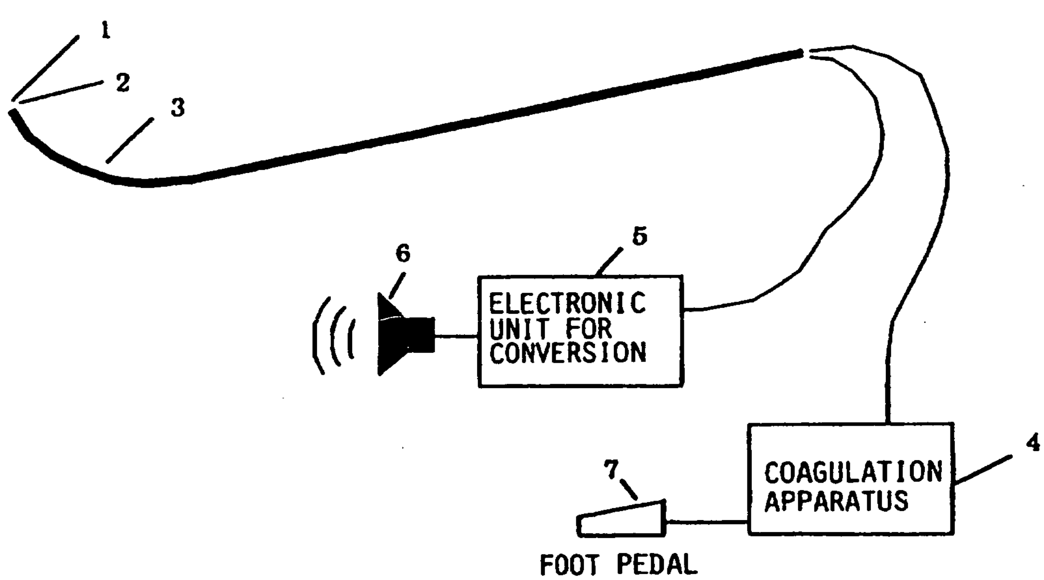
(72) Inventors; and
(75) Inventors/Applicants (*for US only*): GRØNNINGSÆTER, Åge [NO/NO]; Kroppanmarka 112, N-7039 Trondheim (NO). UNSGÅRD, Geirmund [NO/NO]; Erling Skakkes gt. 42, N-7012 Trondheim (NO). KLEVEN, Atle [NO/NO]; Kongens gt. 91b, N-7012 Trondheim (NO). OMMEDAL, Steinar [NO/NO]; Gildheimsv. 11b, N-7044 Trondheim (NO). MÅRVIK, Ronald [NO/NO]; Breisynvn. 13, N-7021 Trondheim (NO).

(74) Agent: LARSEN, Rolf, Chr., B.; ABC-Patent, Siviling. Rolf Chr. B. Larsen a/s, Brynsveien 5, N-0667 Oslo (NO).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
In English translation (filed in Norwegian).

(54) Title: SURGICAL INSTRUMENT



(57) Abstract

Surgical instrument for locating and stopping bleeding during surgical operations, comprising a carrier member having an end portion adapted to be introduced manually to the operation site, and at least one sensor element (1) mounted at the end portion of the carrier member and adapted to detect bleeding. A coagulator device (2) is mounted on or can be introduced through the end portion adjacent to the sensor element (1), and an electronic unit (5) is connected to the sensor element (1) for providing an operator signal (6) during detection and location of a bleeding spot. A coagulation apparatus (4) is connected to the coagulator device (2) for activation (7) thereof in response to said operator signal (6).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

SURGICAL INSTRUMENT

The present invention relates to a new surgical instrument or auxiliary apparatus that can be employed for locating an unintentional bleeding and to stop it. The instrument consists of one or more sensors as well as one or more devices for coagulation. The sensor shall give the operator information regarding the location of the source of bleeding so that the instrument is introduced manually (or automatically) towards the bleeding source and so that the bleeding is stopped by means of a coagulator.

This new instrument will be utilized in situations where unintentional bleeding can occur, but where because of reduced or no visual control the operator is prevented from finding the bleeding in order to stop the same (e.g. within endoscopic surgery). The instrument can be designed in various manners, either as an independent instrument or integrated into another surgical instrument.

Endoscopic surgery in the brain has increased during the recent years since technology has been developed that is suitable for this purpose. These techniques are based upon rigid and flexible endoscopes being provided with a light source, optics and one or more work channels. In the work channel(s) there may be introduced surgical instruments and/or flushing or suction can be performed. Surgical tools or instruments of interest are e.g. diathermic devices, scissors, biopsy forceps, lasers etc. The tool is guided into position by means of optical observation from the tip of the endoscope.

In the brain endoscopic surgery is mainly employed for punctuating cysts (abnormal liquid collection) or for removing small tumors. Since the operation is controlled by means of optical observation from the tip of the endoscope, the employment of endoscopes in the brain is restricted to the immediate proximity of ventricles and cysts. It is not possible to operate in massive brain tissue.

A problem with these operation techniques is uncontrolled ble ding. If accidentally a blood vessel is ruptured this will bleed and in the course of a few seconds the whole

liquid-filled cavity will be filled up with blood. Visibility will be lost for the surgeon and it is not possible to find the bleeding spot or site in order to stop the bleeding. The most common way of solving the problem is to flush with clean water into the cavity and wait until the bleeding has decreased and visibility is sufficient for being able to find the bleeding source and stop it permanently with a coagulation intstrument. Alternatively it may be attempted to stop the bleeding by establishing a counterpressure by inflating a balloon or introducing water at a high pressure. If none of these methods are sucsessful, there must be performed an open surgical operation in order to stop the bleeding.

When a blood vessel is ruptured blood will be pumped out into the liquid-filled cavity. The blood pressure will cause blood to be discharged from the blood vessel at a certain velocity and there will be a jet emitted from the bleeding source. The density of blood is higher than that of the biological water filling the cavity. This means that such bleeding will be somewhat similar to a waterfall, as a jet is pumped out from the vessel and gravity pulls the jet downwards.

The discharged blood will have a temperature close to 37 degrees at the outlet. The liquid in the cavity will have a temperature that can vary between ambient temperature (37 degrees) and the temperature of the flushing liquid being introduced. By selecting a lower temperature of the flushing liquid, e.g. 25 degrees, there may be obtained a temperature gradient between the blood jet and the environment. According to the invention this can be utilized for finding the blood jet by mounting a temperatur sensitive sensor on a movable instrument. At the moment when the sensor is introduced into a blood jet a temperatur increase will be obtained because of heat conduction. The temperature sensor can be connected to a unit which e.g. generates a pipe or whistle signal the frequency of which varies with the temperature. This makes it possible for the surgeon to seek out the blood jet and to follow it to its origin. The blood is quickly

cooled, which means that a small bleeding can only be detected by substantially direct contact and relatively close to its origin.

Endoscopic surgery in the brain is today primarily restricted to liquid-filled cavities. The reason for this is the use of optical observation as guidance. By employing ultrasonic imaging from the surface of the brain and/or from the tip of the surgical instrument (such as the endoscope), it will be possible to a higher degree to operate in massive brain tissue. One can introduce an endoscope to a tumor, bleeding or other lesion and start removal thereof without having a liquid-filled cavity in front of the tip. As the tumor is removed there will be formed a cavity which in addition can permit visual control.

If bleeding occures before a cavity is established, possibly in a small cavity, there will be no well defined blood jet being discharged and sinking like a waterfall. Blood will flow around the instrument in a complicated movement pattern that will make it more difficult to localize by means of a sensor.

According to an embodiment of the instrument according to the invention, this problem can be solved by introducing flushing water through the instrument for the purpose of cooling down the tissue and the blood. By correct selection of liquid temperature one can cool down the outermost layer of tissue which surrounds the instrument. If bleeding arises one continues to flush with water in order to cool the blood quickly and suck this out from the region conserned. Blood which is pumped out from the injured blood vessel will have a higher temperature than the ambient tissue and the water. By moving a temperature sensitive sensor along the wall of the tissue the bleeding can be detected when the sensor is localized in immediate proximity of the bleeding source.

It may be desireable to have a possibility of detecting the bleeding at a larger distance, without the sensor being in contact with the blood. Several solutions are possible, and also a combination of several techniques, such as:

a) An infrared sensor receiving radiation heat from the

blood jet at a distance, will be able to detect the jet at a certain distance.

b) The velocity of the blood can be recorded by means of an ultrasonic Doppler transducer. By sweeping an ultrasonic beam around in the cavity one will be able to detect where there is blood in movement, and in this way the bleeding can be localized.

c) Laser-Doppler is another technology that can be employed.

The method can be utilized within most surgical branches where operations are performed by means of an endoscope or endoscope-like techniques. This includes laparascopic surgery, gastroscopic and bronchoscopic surgery, urology, obstetrics, gynaecology etc. Another possible field of use is during transnasal surgery in the hypophyses whereby the operation takes place through a sleeve of about 15 mm width, being inserted through the nose. Visual observation and access for surgical tools and instruments are restricted by the metal sleeve through which the operation takes place.

Previously known methods and techniques of general interest in this connection, can be regarded as represented by the following patent specifications/literature:

[1] US 4,354,504

[2] Intraoperative use of Doppler ultrasound and endoscopic monitoring in the stereotactic biopsy of malignant brain tomors.

[3] US 4,784,150

[4] WO 94/24948

Besides reference is made to the following patent specifications, which perhaps have somewhat more specific interest than those mentioned above:

[5] US 5,188,111

[6] US 5,085,658

[7] US 5,376,087

[8] US 5,377,683

[9] US 5,275,166

[10] US 5,325,860

[11] US 5,353,783

Certain separate features in technological methods being employed in connection with the instrument according to the present invention, for detecting bleeding, thus are known from other clinical relationships and for other purposes. Two thermosensors have been employed for quantizing blood flow in blood vessels being intact, for monitoring blood flow during an operation [1]. Ultrasonic Doppler has been described during surgical operations in the brain for the purpose of detecting blood vessels in good time so as to avoid a critical situation [2]. Optical techniques have also been employed in order to record blood flow within massive biological tissue [3]. It is common to these methods that they are used for quantizing blood flow in intact blood vessels or for localizing intact blood vessels.

Methods for coagulating blood vessels in order to stop bleeding are per se well-established techniques being employed in various relationships, also endoscopically. Both unipolar and bipolar diathermy, laser and other methods are used. The present invention comprises the utilization of such known techniques in combination with a sensor for detecting a bleeding. What is novel here is the combination of a sensor and a coagulator for detecting and stopping an unintended bleeding in surgical relations, based upon a manual instrument which preferably is conventional or of a common standard type.

There has previously also been described a method of closing blood vessels that have been deliberately perforated [4]. After intervention in an artery the opening in the vessel must be closed in order to avoid bleeding. This can be done by introducing a balloon in the vessel for keeping the vessel wall in place while a bipolar forceps-like device burns or coagulates the vessel wall from the outside. The purpose of this known method is to prevent an uncontrolled bleeding, but at the same time to maintain the blood flow in the vessel.

To [5] it is to be remarked in particular that this patent specification gives a rather general description of a

search or detection system for many different uses, and involves a quite complicated and automatic control of a catheter or some other form of sonde. Patent specification [6] is directed to an operation tool based on visual control and having means for bleeding control, but without any sensor for detecting bleeding. Patent specifications [7] and [8] relate to methods and techniques corresponding more or less to the contents of the two patent specifications just referred to above.

On the above background there is according to the invention, provided an advantageous new surgical instrument the novel and specific features of which consist in the first place in a carrier member with an end portion adapted to be introduced manually to the operation site or cavity, at least one sensor element mounted at the end portion of the carrier member and adapted to detect bleeding and to localize a source of bleeding, a coagulator device being mounted on or being adapted to be introduced through the end portion adjacent to the sensor element, an electronic unit connected to the sensor element for providing an operator signal during detection and localizing of a bleeding, and a coagulation apparatus connected to the coagulator device for activation thereof in response to said operator signal.

In this context the carrier member can be a preferably rigid, elongated element that can be used for bringing the sensor and the coagulator to the desired position during the operation. In certain embodiments such a carrier member can consist of a more or less conventional endoscope or it can be combined with an endoscope. The endoscope itself can be rigid or flexible and comprise one or more elements being common to endoscopes, such as a source of light, optics and at least one work channel.

In addition to being based upon effects as mentioned above, the sensor element can also comprise a laser fibre or an acoustic transducer for (passive) detection of acoustic waves emanating from the bleeding.

The instrument according to the invention can be made rigid or flexible in miniature design in order to be intro-

duced through a work channel in an endoscope, e.g. a tool in the form of scissors, biopsy forceps, laser, ultrasonic aspirator, diathermic device and so forth.

According to the invention it is particularly preferred in many connections to let the design of the instrument be based upon a mechanically rigid carrier member which is incorporated in a common or conventional surgical instrument, such as diathermic forceps or biopsy forceps. Additional advantageous embodiments are obtained by combining such a standard instrument with a replaceable sleeve member carrying the sensor element at an outer end thereof.

The coagulator device at the tip or end portion of the carrier member, according to particular embodiments of the instrument according to the invention, can comprise unipolar or bipolar diathermic electrodes. Another possible form of coagulator consists in a laser fibre connected to a suitable laser. In such case the laser can be considered to belong to a coagulation apparatus serving to drive or energize the coagulator device referred to. The apparatus in general can be e.g. an electric diathermy apparatus or an argon beam instrument.

Thus the actual surgical instrument according to the invention advantageously is adapted to be manually movable.

The operator signal referred to can be presented as an audible signal or visually as the excursion of a pointer or as varying light intencity, blinking or the like, possibly as a mechanical or electrical stimulation of the skin, e.g. at the hand of the surgeon.

As regards the bleeding to be detected, the blood discharge may have the form of a jet entering into a liquid-filled cavity. The blood flow or jet is characterized by a certain velocity, a cross section, density, direction and temperature. These parameters are in part determined by the blood pressure, blood viscosity and the size of the cut or rupture in the blood vessel concerned.

In the following description the invention will be explained more closely with reference to the drawings, in which:

Fig. 1 schematically and simplified shows a surgical instrument based upon the invention, with associated equipment or units,

Fig. 2 shows in an larged perspective view the outer end of a carrier member incorporated in the instrument according to an embodiment of the invention,

Fig. 3 shows another embodiment in a corresponding way as Fig. 2,

Fig. 4 shows the situation in an operation cavity with a bleeding and an instrument according to the invention introduced into the cavity,

Fig. 5 shows a specific embodiment of electronic circuits for providing an audible operator signal,

Fig. 6 shows an alternative embodiment of electronic circuits for providing and audible operator signal,

Fig. 7 shows a specific embodiment of the instrument according to the invention, based upon a bipolar diathermic forceps,

Fig. 8a shows the movable carrier member of an instrument according to a further embodiment of the invention,

Fig. 8b shows in more detail and in perspective view the outer end portion of the carrier member in Fig. 8a,

Fig. 9 shows a design of the end portion of the carrier member, whereby sensor and coagulator means are introduced through a work channel in an endoscope,

Fig. 10 shows an embodiment where an endoscope tip or end portion has a sensor element and a coagulator device integrated into its structure,

Fig. 11 shows an embodiment being somewhat modified in relation to the one in Fig. 10, i.e. with a coagulator device introduced through a work channel in an endoscope,

Fig. 12 shows a simplified and schematic system for full or partial automatic control of the surgical instrument according to the invention, in order

that the tip or end portion thereof shall seek toward a bleeding and the actual bleeding source,

Fig. 13a shows a further embodiment of the instrument according to the invention, based upon a biopsy forceps of substantially conventional form,

Fig. 13b shows in more detail how the tip of the instrument in Fig. 13a can be designed,

Fig. 14a shows a separate sleeve provided with a sensor and adapted to be mounted on a manual surgical instrument,

Fig. 14b shows the sleeve member in Fig. 14a as mounted on a biopsy forceps,

Fig. 14c shows in detail an advantageous design of the tip of the instrument in Fig. 14b,

Fig. 14d shows the same detail as Fig. 14c, but in lateral view and with the sleeve member retracted,

Fig. 14e shows the same detail as Figs. 14c and 14d, but with the sleeve member pushed forward,

Fig. 15a shows a similar, separate sleeve member as in Fig. 14a, but being additionally provided with flushing and suction channels,

Fig. 15b shows the sleeve member in Fig. 15a mounted on a biopsy forceps, and

Fig. 15c in further enlargement shows the tip of the sleeve member in Figs. 15a and 15b.

Fig. 1 shows a catheter-like combination instrument based upon a carrier member 3 having at least one sensor 1 and at least one coagulator 2 at its tip, which can be flexible and controllable. The combination instrument 3 is connected to a coagulation apparatus 4 which is activated by a pedal 7. Moreover the combination instrument 3 is connected to an electronic unit 5 for converting the sensor signal into an operator signal. E.g. the operator signal can give information back to the operator through a loudspeaker 6 whereby an incr asing temperature can give an increased frequency of a whistle tone. The bleeding can e.g. also be detected by an ultrasonic Doppler signal converting blood velocity to an acoustic signal. Moreover bleeding can be

detected by an optical Doppler signal converting blood velocity to an acoustic signal.

A possible design of the tip or end portion 3A of the combination instrument 3 is shown in Fig. 2, where the sensor 12 is a thermo-element and localized at the middle of the cross section, whereas electrodes for diathermy are localized around the circumference. In this embodiment there are two electrodes 10 being connected to one of the conductors to the diathermy apparatus (indicated with the symbol "-") and two electrodes 11 being connected to the other conductor (indication "+").

Other embodiments of the diathermic coagulator can be more efficient, e.g. a design where two electrodes project somewhat from the tip so that they penetrate somewhat into the tissue at a light pressure. In this manner the electrodes will be able to enclose the vessel somewhat more in similarity to what is obtained with bipolar diathermic forceps.

In Fig. 3 the sensor at the tip of the combination instrument 3 consists of two ultrasonic transducers, i.e. one for emission 21 and one for reception 22. Electrodes 10 and 11 for diathermy can be as described with reference to Fig. 2.

Fig. 4 shows a typical situation for use of the combination instrument 3, where this is positioned within a liquid-filled cavity 42 which e.g. lies within massive brain tissue 43. Here the liquid is biological salt water. A blood vessel has been subjet to a leakage and emits a blood jet 41 into the liquid-filled cavity 42 from the bleeding source 40. Blood jet 41 will be deflected downwards because of gravity and the fact that blood has a higher density than biological salt-water which fills the cavity 42.

Fig. 5 shows a possible implementation of the electronic unit 5 for converting a sensor signal to an observer signal as well as means for giving the observer information back 6. A thermo-element 50 represents a heat sensitive electrical resistor which is connected to a voltage divider and an electronic amplifier 51. The amplifier has an

electric voltage output applied to the voltage/frequency converter 52. Converter 52 delivers a voltage to a piezo-electric element 53 which provides for an audible signal.

The temperature of the thermo-element is converted to a whistle tone the frequency of which is proportional to the temperature. In the amplifier adjustment can be made both with respect to amplification and zero level, so that the sensitivity and the frequency of the instrument at a given temperature can be adjusted.

Fig. 6 shows an implementation of the electronic unit 5 in Fig. 1 based upon continuous ultrasound Doppler measurement (CW Doppler). An emitter transducer 21 is connected to an ultrasonic transmitter 61. A receiver transducer 22 is connected to a receiver 62 which is further connected to a Doppler processing unit 63 delivering an acoustic observer signal in loudspeaker 64. This method makes it possible to measure the velocity of the blood jet, but there will not be presented any information with respect to the distance to the blood jet.

As an alternative one can use only one ultrasound transducer and transmit and receive at the same transducer by employing pulsed Doppler techniques (PW Doppler). This method additionally gives the possibility of determining the distance to the blood jet by measuring the Doppler shift a certain time after each emitted pulse.

Fig. 7 shows a possible implementation of a self-contained surgical instrument consisting of a bipolar diathermic forceps 71 having an electric connection 72 for the coagulation instrument. Accordingly forceps 71 constitute the carrier member of the instrument. Electrodes 74 for diathermy are mounted at the tip of forceps 71, and a sensor 73 is mounted at one of the electrodes. Various configurations can be contemplated, where one or more sensors are mounted at one or both electrodes. E.g. a laser or ultrasonic Doppler sensor can be mounted at one electrode and a thermistor at the other electrode. The Doppler sensor is used to localize bleeding at a distance, whereas the thermo-element is used adjacent to the bleeding source when the tip

of the instrument is positioned in the blood jet.

Experiments show that the blood is quickly cooled when it flows out into a liquid-filled cavity having a lower temperature than the blood. Besides the blood jet as a rule will have a small cross section. This means that it is difficult to detect the blood jet with a temperature sensitive sensor. There will be no significant sensor signal until the sensor is positioned in the actual blood jet, as this restricts the detection capability.

One way of improving this can be to incorporate suction means in the instrument, so that this will exert a moderate suction effect at the tip where the sensor is positioned. Thus, parts of the blood jet can be moved towards the catheter although this is positioned at a certain distance from the blood jet.

Fig. 8a shows how sensor and coagulator can be mounted at the tip 82 of a carrier member in the form of a flexible and controllable suction element 81. In this way several functions can be combined in one instrument and there will be a reduced need for changing instrument if bleeding occurs. A flexible suction element or tool will be applicable in several types of minimal invasive surgical operations, inter alia during evacuation of intracerebral brain bleeding through a thin (4-8 mm) channel in the normal brain (sound brain part). During such operations there is a requirement for tearing loose fragments of coagulated blood being adhered to the brain wall.

The proximal end of the instrument consists of a handgrip 83 having a device 84 for controlling the flexible tip 82, as well as connections for suction 85, coagulator 86 and sensor 87.

Fig. 8b shows a possible implementation where two sensors 88 (e.g. two thermistors), are mounted between two bipolar diathermic electrodes 89 around a suction channel 89b at the tip of the catheter 81.

Fig. 9 shows an embodiment in which the instrument is introduced through a work channel 95 in an endoscope 91. At the tip of the endoscope there can be provided e.g. a light

source 93 (optical fibre), optics 92 and a channel 94 for flushing and/or suction. Other functions can also be present in the endoscope, e.g. separate channels for flushing and suction. The instrument is guided through the work channel 95. In the example shown, the instrument is a biopsy forceps 96 with a sensor 97 mounted to one of the teeth and with bipolar electrodes 98 mounted on both teeth.

Biopsy forceps are regularly used in the work channel of endoscopes. By integrating a sensor and a coagulator into such biopsy forceps it will be possible to localize and stop bleedings without changing the endoscope or the tool in the work channel when bleeding occurs. This is important since it is difficult to seek back to the same spot if the endoscope is removed, and the visibility is poor or zero.

Fig. 10 shows a possible embodiment in which sensor and coagulator are integrated at the tip of an endoscope 101. Also here the endoscope is provided with optics 102, light source 103, channel 104 for flusing and/or suction, and at least one work channel 105. A sensor 106 such as the end of a laser fibre, is also mounted at the end surface of the endoscope, whereas bipolar electrodes 107 are placed along the circumference of the endoscope tip.

A higher coagulation effect will be obtained if the electrodes can be made movable to enclose the bleeding vessel. This can be implemented in various ways:

i) Two or more electrodes lie in recesses in the endoscope, possibly at the outside thereof, and are moved forward before use. The electrodes are urged into the tissue around the bleeding vessel by moving the endoscope forwardly. Coagulation is started. The effect will be still higher if in addition the electrodes could be clamped together around the bleeding vessel and exert a pressure on the vessel structure.

ii) Two or more electrodes can be articulated at the tip of the endoscope so that they are pointing backwardly (away from the tip, e.g. in recesses in the endoscope wall). When there is a requirement for coagulating, these will be folded forwardly and pressed into the tissue around the

bleeding vessel, by moving the endoscope forwardly. In addition thereto the electrodes can be pressed towards each other in order to exert a pressure on the vessel structure for starting the coagulation.

Fig. 11 shows a possible embodiment in which a sensor 115, which is e.g. based on a laser, is integrated into the tip of an endoscope 111, while a coagulator 117 is mounted on a thin tool element 116 being introduced through a work channel 118. As previously described the endoscope has optics 112, light source 113 and channel 114 for flushing and/or suction. The coagulator device can e.g. consist of two bipolar diathermic electrodes 117 mounted at the tip of element 116. The coagulator can also be a laser fibre, biopsy forceps with bipolar electrodes as described, a unipolar diathermic device or the like.

Fig. 12 shows a possible embodiment wherein the carrier member 120 of the instrument contains three wires being attached to the tip of the carrier member. A tip 121 is flexible and controllable in a hemispherical region by means of three servomotors 122. The whole catheter/carrier member 120 or only the flexible tip can be moved along the catheter axis by means of a separate servomotor 123 as mentioned above.

The servomotors are controlled manually from a control unit 124 which is operated by the operator with at least one operating device, e.g. a control stick 125 or a 3D mouse. The instrument can be controlled directly by the operator without any form of automatic means in that the angular movements of the control stick determines the degree of deflection of the catheter tip, whereas e.g. two push buttons control the longitudial movement. The operator takes advantage of an operator signal 126 from converter 127 as a guide in seeking the bleeding.

Control unit 124 can then in cooperation with an imaging apparatus 128 (e.g. based on ultrasound) provide three dimensional images of the cavity.

In the simple and advantageous example being illustrated in Fig. 13a, there is shown a selfcontained, manual

instrument consisting of a biopsy forceps the rod-shaped part 131 of which constitutes a carrier member, as explained above. This rod-shaped carrier member 131 projects from a handgrip as generally denoted 130 and is operated by the surgeon. The functional elements in Fig. 13a are in general shown at 134 at the outer end of rod part 131. Fig. 13b shows more in detail the design at the tip of rod or carrier member 131, i.e. two movable jaws or teeth 134A and 134B forming therebetween a gap. The drawing here shows these teeth 134A/134B in an open position. A sensor element 133 is shown at the outer end of tooth 134A. For the electrical signal from sensor 133 Fig. 13a shows a terminal 139 for a further connection to electronics incorporated in a complete system.

Two electrodes 137A and 137B are mounted each on one of the two teeth 134A and 134B. The electrodes are adapted to cause a coagulating effect by diathermy. For current supply to the electrodes Fig. 13a shows a terminal 138 at the operating handgrip. Diathermic electrodes as mentioned here can be unipolar or bipolar. With electrically connective teeth and an electrically insulated rod or carrier member 131, the gap between the teeth can constitute a unipolar diathermic electrode. As an alternative bipolar diathermy can be provided for by mounting an insulating electrode at one of the teeth, whereas the rest of the jaw or gap can constitute the other electrode. The possibilities of variations in this connection are large, but Figs. 13a and 13b represent a favourable design in which the coagulator device, in particular one or two electrodes therein, are movable in relation to each other or in relation to the carrier member.

Figs. 14a,b,c show an embodiment with specific advantages, based upon a separate, sleeve-shaped carrier member 141 adapted to be mounted (Fig. 14b) on a rod-shaped part belonging to a biopsy forceps 140 or similar standard instrument for surgical use. The outer end of sleeve member 141 has a sensor element 143 being electrically connected to a terminal 148 at the opposite end of the sleeve member.

Advantageously sleeve member 141 is replaceable and together with the rod-shaped part of the biopsy forceps constitute a combined carrier member having the same function as the above described carrier members. More particularly sleeve member 141 is adapted to be pushed onto the instrument rod part 140, which can be done before the surgeon begins an operation, so as to use the sleeve during the whole operation, or it can be mounted if and when a bleeding occurs.

As in the biopsy forceps of Fig. 13a the embodiment of Fig. 14b has a jaw-shaped coagulator device 144 which is to cooperate with sensor element 143. Coagulation can be based upon unipolar or bipolar diathermy or other principles as described above.

In more detail Fig. 14c shows how sensor element 143 suitably can be positioned at a small distance (a few millimeters) retracted from the outer end of coagulator device 144. While this is shown from the side in Fig. 13b, it is seen directly from above in Fig. 14c. Moreover it is seen from Fig. 14c that sensor 143 is supported by a projection 143A at the end of sleeve member 141, and protrudes in the longitudinal direction thereof. Preferably the projection and thereby sensor 143 is positioned a few millimeters laterally from the plane in which the jaws or tooth in coagulator device 144 move. In the situation illustrated in Fig. 14c coagulator device 144 is engaging a blood vessel, and more particularly a blood vessel fragment 145 at one side of a bleeding source 149, with the blood vessel continuing at the other side in the form of vessel fragment 146. Accordingly in the situation shown, the coagulating function will be favourable after the sensor 143 has localized the bleeding source 149.

In many cases the surgeon can have great advantage from a structure with a displaceable sleeve member 141, as illustrated in Figs. 14d and 14e. The latter Figure shows sleeve memb r 141 in a position pushed forward on rod member 140, so that sensor element 143 is located in a position relative to coagulator device 144 corresponding substan-

tially to the relationships in Figs. 14b and 14c. Fig. 14d, however, shows sleeve member 141 retracted so that sensor 143 is mainly removed from the region where coagulator jaws 144 with their electrodes 147 act. It is obvious that such a displaceable sleeve member 141 can be adjustable without steps in its longitudinal direction, or possibly can be adapted to assume certain fixed possitions, e.g. provided by means of snap elements. In the retracted position in Fig. 14d sensor element 143 with its associated projection 143A will not significantly impede the visibility for the surgeon and the same applies to the normal function of the standard instrument concerned, such as a biopsy forceps having a main part or rod-shaped member 140 as discussed above.

During laparascopic operations the surgeon often uses a separate instrument which makes it possible to flush with biological salt water as well as to apply suction for removing water, blood and possible small biologic fragments. Such an instrument can be introduced through one or more work sleeves which e.g. punctuate the abdomen during abdominal operations. For obvious reasons it is desired to keep the number of such punctuations or through-passages at a minimum. Figs. 15a, 15b and 15c show a specific solution according to the invention, for such situations or operations.

As a starting point Figs. 15a and 15b correspond to Figs. 14a and 14b, as a manual instrument such as a biopsy forceps 150 is provided with a replaceable sleeve member 151 having a sensor element 153 with an associated electrical terminal 158 and besides there is indicated an end portion 152 at the outer end of sleeve 151. At 154 in Fig. 15b there is indicated a coagulator device having e.g. jaws or teeth like the device 144 in Fig. 14b-14e.

As will be seen in particular from Fig. 15c sleeve member 151 is provided with several through-going channels in the longitudinal direction, and these channels have openings in an outer end wall at portion 152. One channel 152A can be utilized for flushing effect and another channel 152B can be utilized for suction, as known per se in surgi-

cal methods. Corresponding outlets or connections at the opposite, inner end of sleeve member 151 are shown at 155 and 156 in Fig. 15a and 15b. At 155 and 156, respectively, it will thus be possible to connect hoses for the flushing and suction respectively, as mentioned.

Furthermore it is seen from Fig. 15c that a third and larger channel or passage 152C extends through the whole length of sleeve member 151, namely for the mounting of the sleeve member on the rigid, rod-shaped part (not shown) incorporated in the manual instrument 150, in the same way as explained with respect to instrument 140 in Fig. 14b-14e. Also sleeve member 151 can be made to be not only replaceable, but also displaceable in its longitudinal direction in relation to the main part of instrument 150.

With the latter specific solution three functions will be combined in one and the same instrument, namely:

- Possibility of localizing and stopping bleeding by means of sensor element 153 and coagulator device 154,
- flushing and/or suction through channels 152A and 152B,
- normal use of the surgical instrument, e.g. as the so-called "grasping forceps".

Such a combined instrument which comprises the posibility of flushing and/or suction as well as localizing of bleeding by means of a sensor element, may also be employed within other fields than laparascopic surgery.

As will be seen further from Fig. 15c the instrument channel 152C is so located that its mouth is ajacent to the projection 153A which carriers sensor element 153. Thus it will be possible to adjust the geometrical relationships in a corresponding way as explained with reference to Figs. 14c, 14d and 14e. It is obvious that the two channels 152A and 152B for flushing and suction respectively, can be replaced by one common channel, where flushing and suction must take place in sequence. Besides such channels can be arranged in various manners. It may be expedient, inter alia, to have several inlets for the suction channel distributed over end portion 152, so that this will not so easily be clogged when contacting biologic tissue.

Another particularly preferred embodiment of the instrument according to the invention is based upon a flexible carrier member which can be introduced through the work channel in a flexible and controllable endoscope. The instrument can be designed essentially as shown in Figs. 13a and 13b, with the modification that shaft 131 is made flexible instead of being rigid. A sensor and a device for coagulation can be designed as previously described, whereby one possible example is given by Fig. 13b. By introducing the instrument through the work channel in an endoscope, the tip of the instrument will be controllable in that the tip of the endoscope is manually controllable, and in that the instrument can be pushed out and inwards through the work channel. It is also possible to have a sensor and a coagulator mounted on the instrument, which according to the kind of operation, shall be used in the work channel, so that if a bleeding occurs it will not be necessary to change instrument. Alternatively the instrument can be designed only for the purpose of localizing and stopping bleeding. In such case the operator must change instrument when bleeding occurs.

In the above description and in the drawings it has been explained that the fundamental inventive idea can be implemented in various manners in practical designs of this new surgical instrument. It is obvious that further variants and modifications are also possible within the framework of the invention. Such a variant can consist in the mounting of sensor elements on lateral surfaces of the end portion of the carrier member, instead of mounting on the end surface as illustrated in the drawings.

C l a i m s

1. Surgical instrument for locating and stopping bleeding during surgical operations,
c h a r a c t e r i z e d by a carrier member (3,71,81,91,101,111,120,131,141,151) having an end portion (3A,152) adapted to be introduced manually to the operation site or cavity (42),
at least one sensor element (1,12,21,22,50,73,88,106,115,-133,143,153) mounted at the end portion (3A,152) of the carrier member and adapted to detect bleeding (41) and to locate a bleeding source (40),
a coagulator device (2,10,11,74,89,98,107,117,137,147) being located on or being able to be introduced through the end portion (3A) adjacent to the sensor element (1,12,21,22,50,-73,88,106,115,133,143,153),
an electronic unit (5,51,52,63,127) connected to the sensor element (1,21,22,50) for providing an operator signal (6,53,64,126) during detection and location of a bleeding (41), and
a coagulation apparatus (4) connected to the coagulator device (2) for activation (7) thereof in response to said operator signal (6).

2. Surgical instrument according to claim 1,
c h a r a c t e r i z e d in that the sensor element (12,73,88) is heat sensitive.

3. Surgical instrument according to claim 2,
c h a r a c t e r i z e d in that the sensor element is sensitive to heat radiation.

4. Surgical instrument according to claim 1,
c h a r a c t e r i z e d in that the sensor element comprises an ultrasonic transducer (21,22) or a laser fibre connected to a laser (106,115) for measuring Doppler shift from blood flow being due to said bleeding.

5. Surgical instrument according to claim 2 or 3, c h a r a c t e r i z e d in that the carrier member (101,111,151) comprises a flushing channel (104,115,152A) for conveying a liquid to said end portion.

6. Surgical instrument according to anyone of claims 1-5, c h a r a c t e r i z e d in that the electronic unit (5) is adapted to convert the output signal from the sensor element (1) to an operator signal (6,64) that can be perceived by the surgeon, e.g. as a pipe tone of varying frequency depending upon said output signal.

7. Surgical instrument according to anyone of claims 1-6, c h a r a c t e r i z e d in that the coagulator device or parts thereof, in particular an electrode or electrodes (74,98,137A/B,147) is (are) movable in relation to the carrier member (71,91,96,131,141), or in relation to each other.

8. Surgical instrument according to anyone of claims 1-7, c h a r a c t e r i z e d in that the coagulator device comprises at least one electrode (10,11,74,89,98,107,117) for providing a diathermic effect.

9. Surgical instrument according to anyone of claims 1-7, c h a r a c t e r i z e d in that the coagulator device comprises at least one laser fibre connected to a laser for emitting coagulating radiation.

10. Surgical instrument according to anyone of claims 1-8, c h a r a c t e r i z e d in that the carrier member (71,131,141,151) is mecanically relatively rigid and preferably is provided in the form of a conventional surgical instrument, e.g. a bipolar diathermic forceps or biopsy forceps. (Fig. 7, 13a,14b,15b).

11. Surgical instrument according to anyone of claims 1-10, c h a r a c t e r i z e d in that the carrier member (81,101,111,151) comprises a suction channel (89b,104,114,152B) having an opening at said end portion.

12. Surgical instrument according to anyone of claims 1-11, c h a r a c t e r i z e d in that the carrier member (96) is sufficiently thin to be introduced through a work channel (95) in an endoscope (91). (Fig. 9).

13. Surgical instrument according to anyone of claims 1-11, c h a r a c t e r i z e d in that the sensor element (106) and the coagulator device (107) are mounted at the tip of an endoscope (101), which thereby constitutes said carrier member. (Fig. 10).

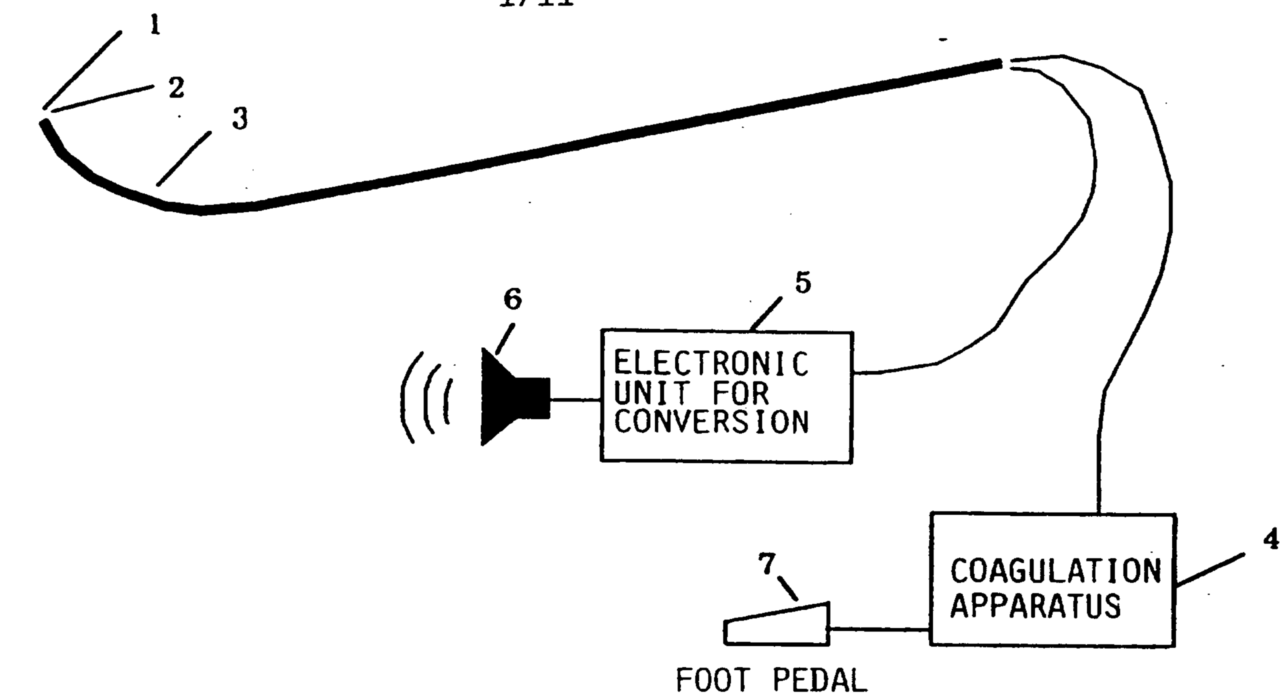
14. Surgical instrument according to anyone of claims 1-11, c h a r a c t e r i z e d in that the sensor element (115) is located at the tip of an endoscope (111), and that the coagulator device (117) is provided at the end of a thin tool element (116) adapted to be introduced through a work channel (118) in the endoscope (111). (Fig. 11).

15. Surgical instrument according to anyone of claims 1-11, c h a r a c t e r i z e d in that there is provided an exchangable sleeve member adapted to enclose a rod-shaped part belonging to a conventional surgical instrument (140,150), so as together with the rod-shaped part to constitute said carrier member, and that the sleeve member at an outer end (152) carries the sensor element (143,153).

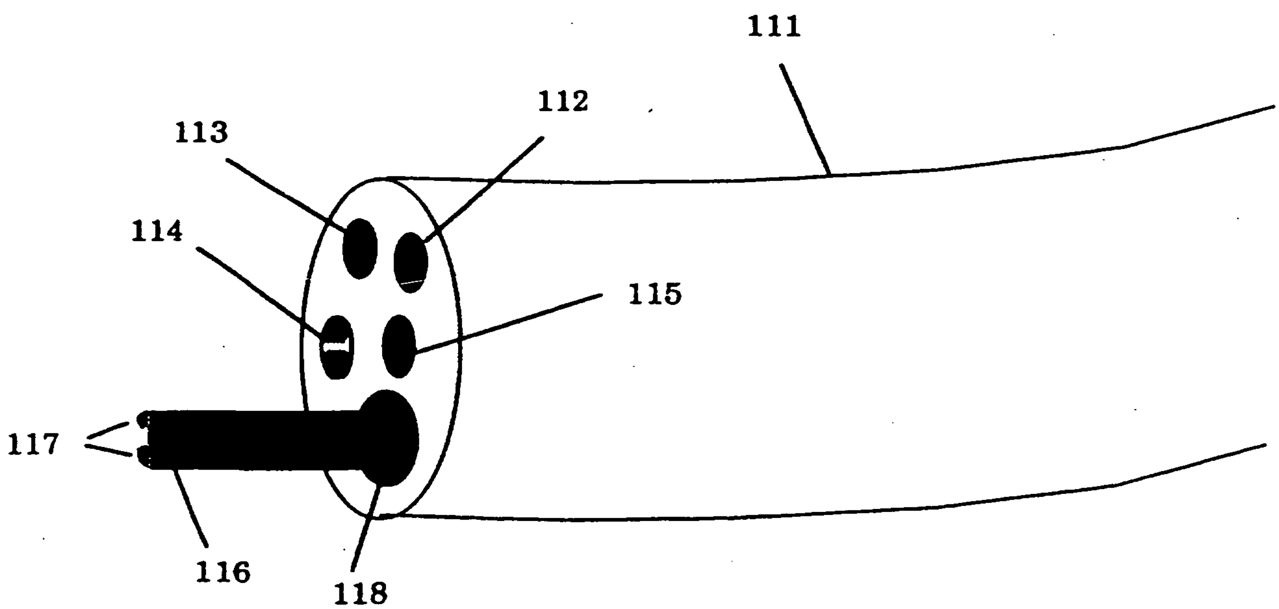
16. Surgical instrument according to claim 15, c h a r a c t e r i z e d in that the sleeve member (141,151) is displaceable longitudinally on the rod-shaped part (140,150), for positioning the sensor element (143,153) in more or less forwardly prodjecting positions.

17. Surgical instrument according to claim 15 or 16, c h a r a c t e r i z e d in that the sensor element (143,153) is mounted on a projection (143A,153A) in the longitudinal direction in front of and from sleeve member (141,151).

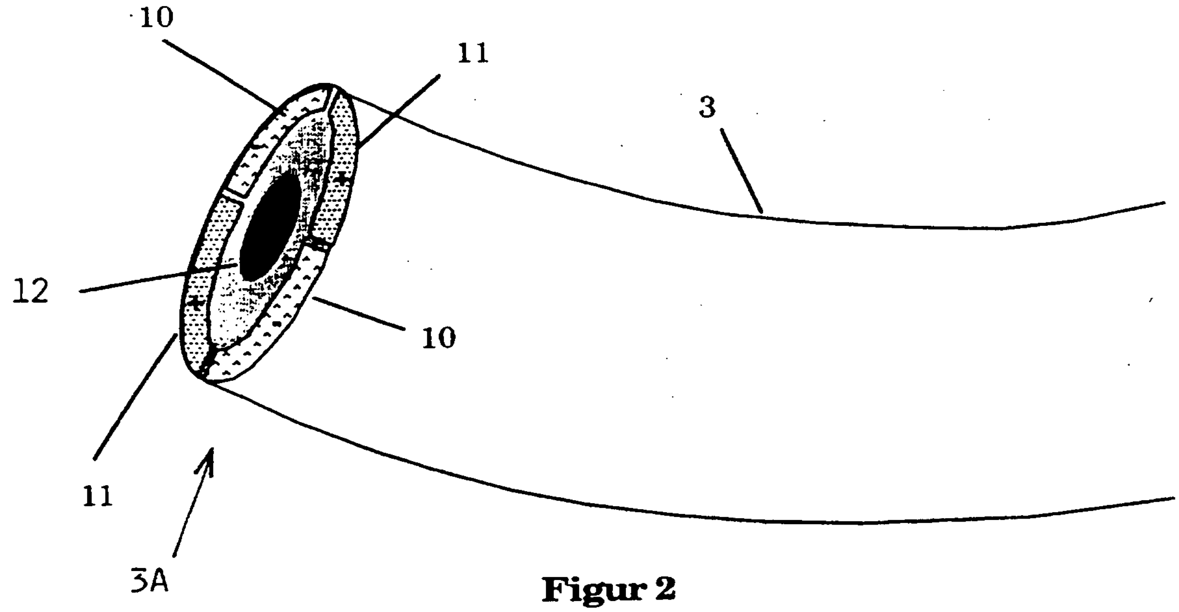
18. Surgical instrument according to claim 15, 16 or 17, c h a r a c t e r i z e d in that through the sleeve member (151) and in the longitudinal direction thereof there is provided at least one channel (152A,152B) for a flushing effect and/or a suction effect as known per se.



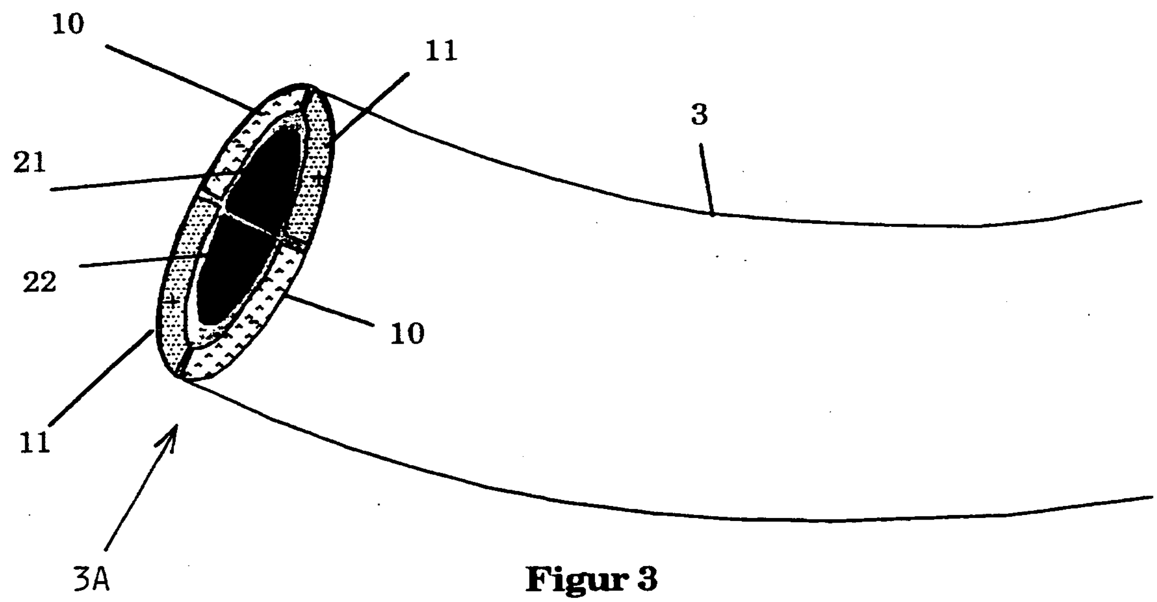
Figur 1



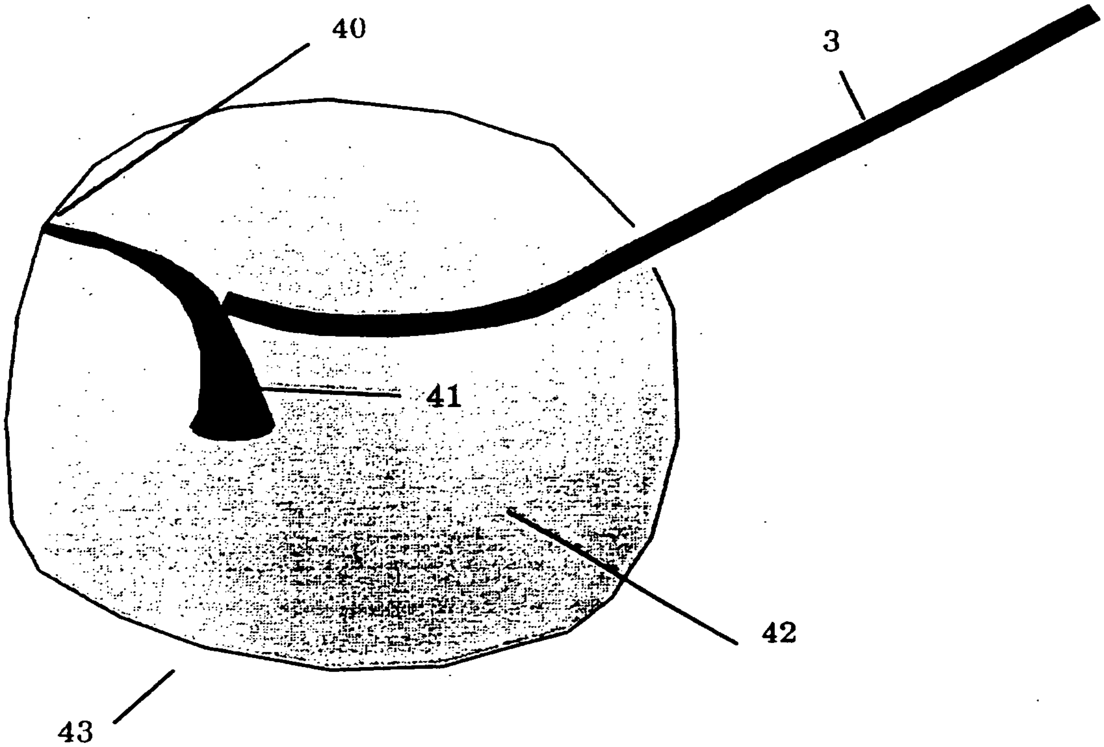
Figur 11



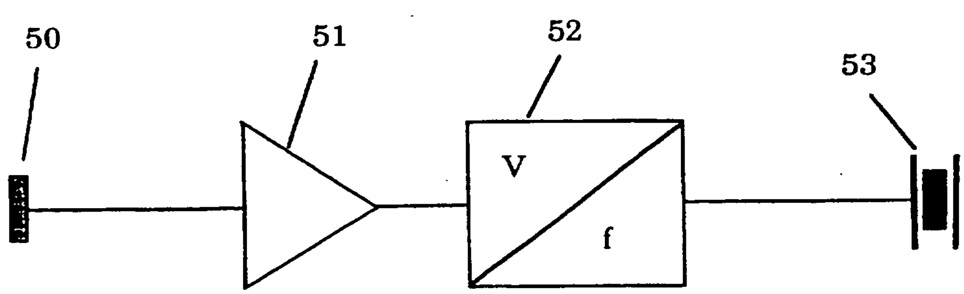
Figur 2



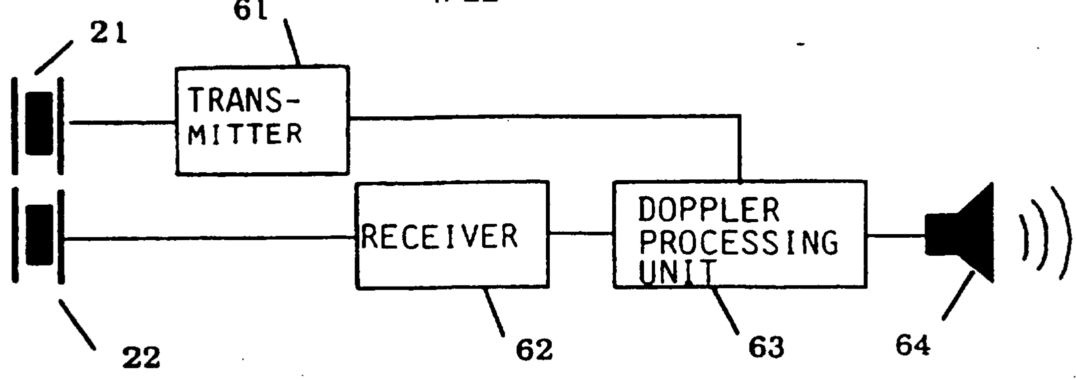
Figur 3



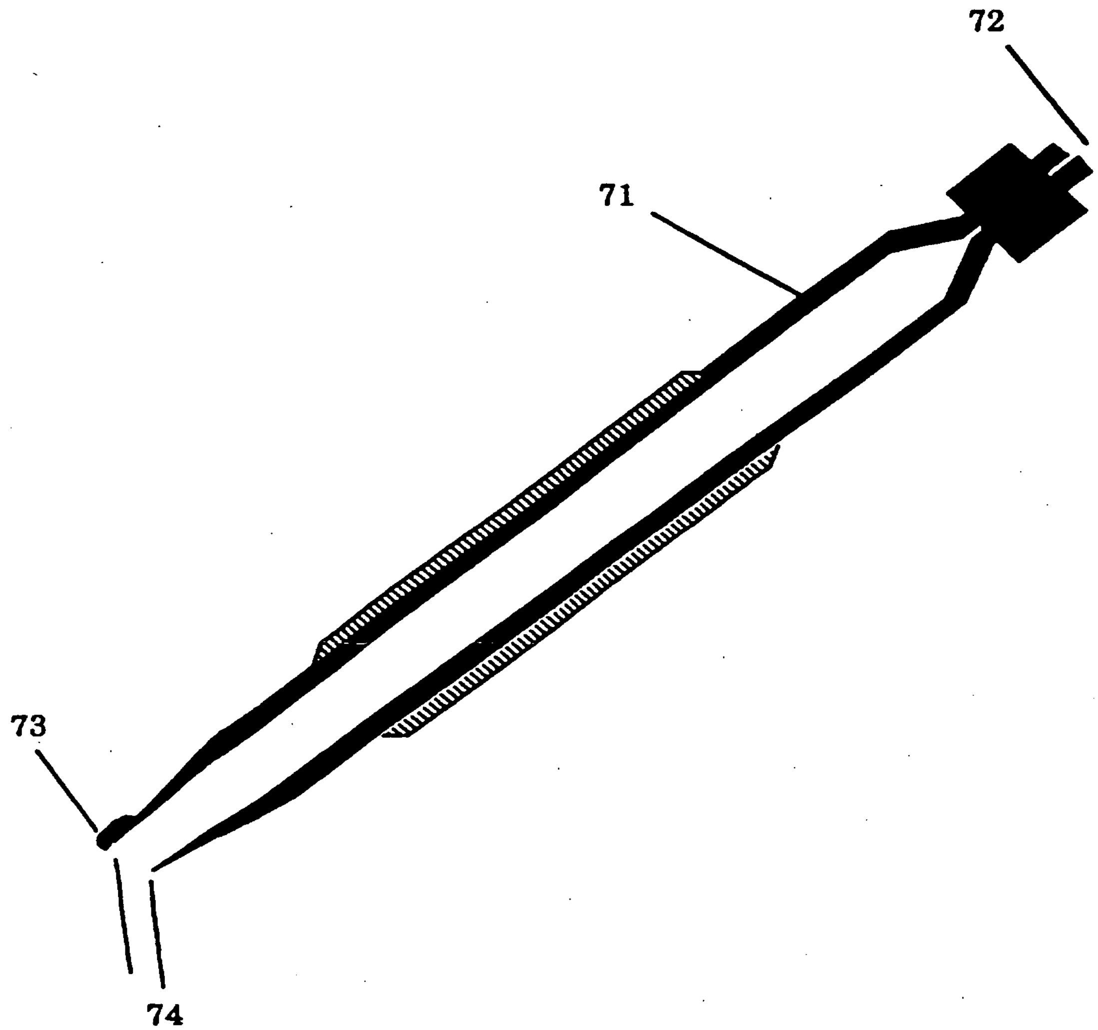
Figur 4



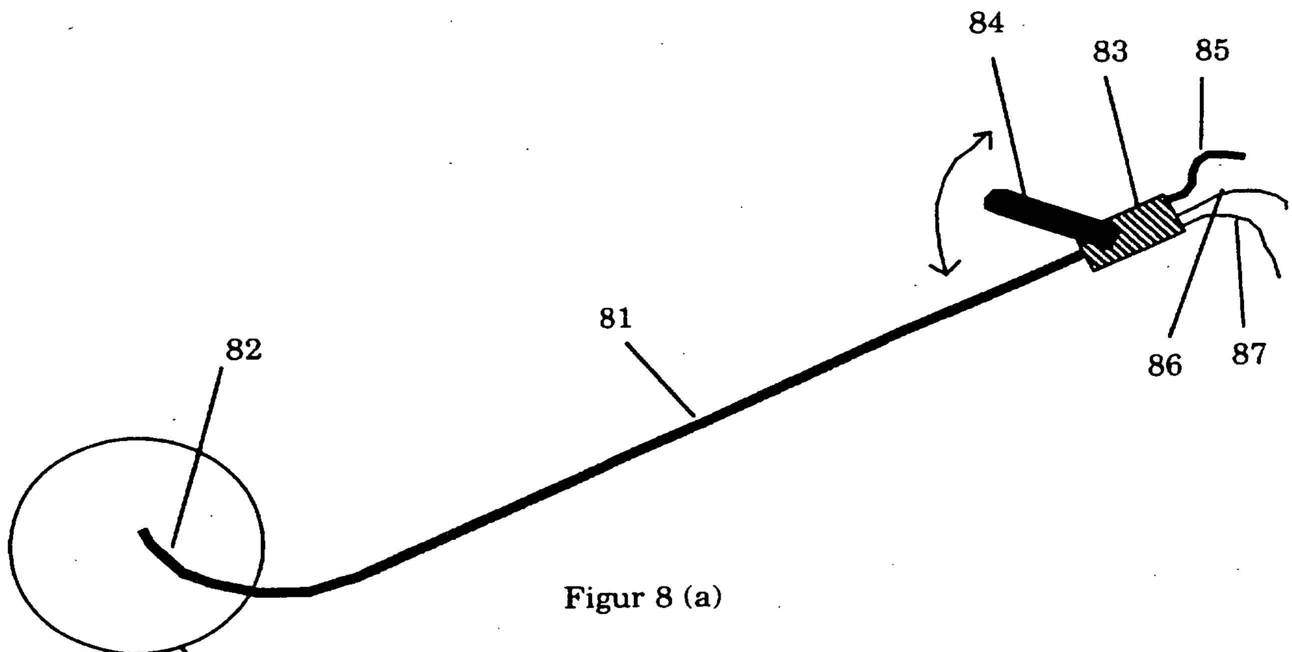
Figur 5



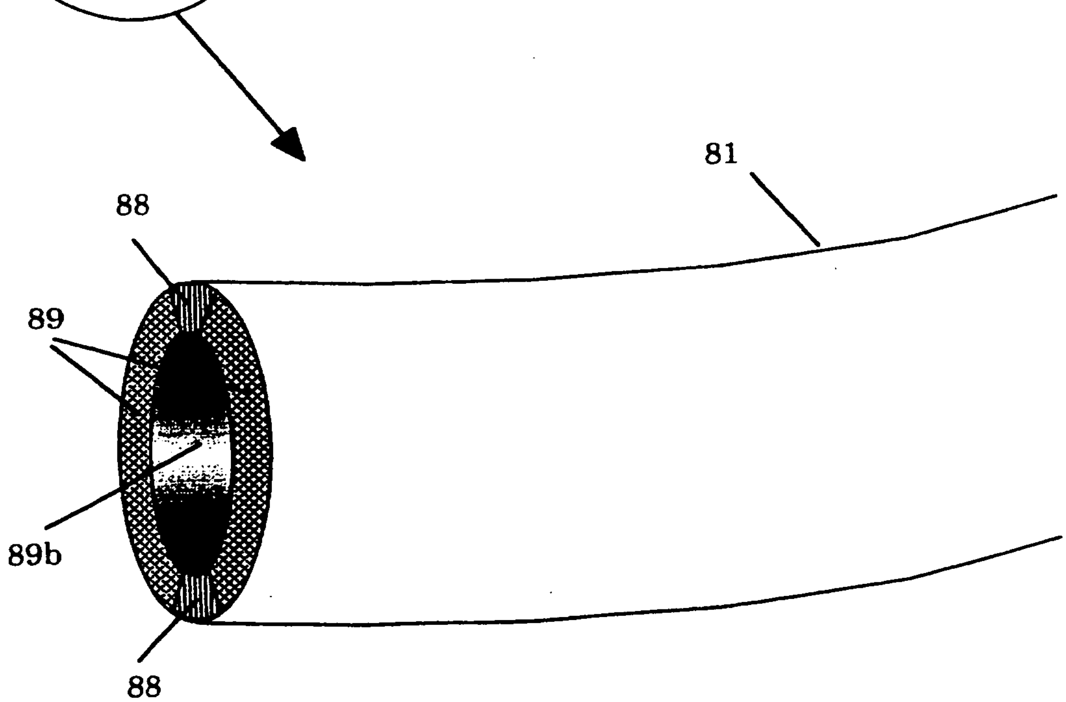
Figur 6



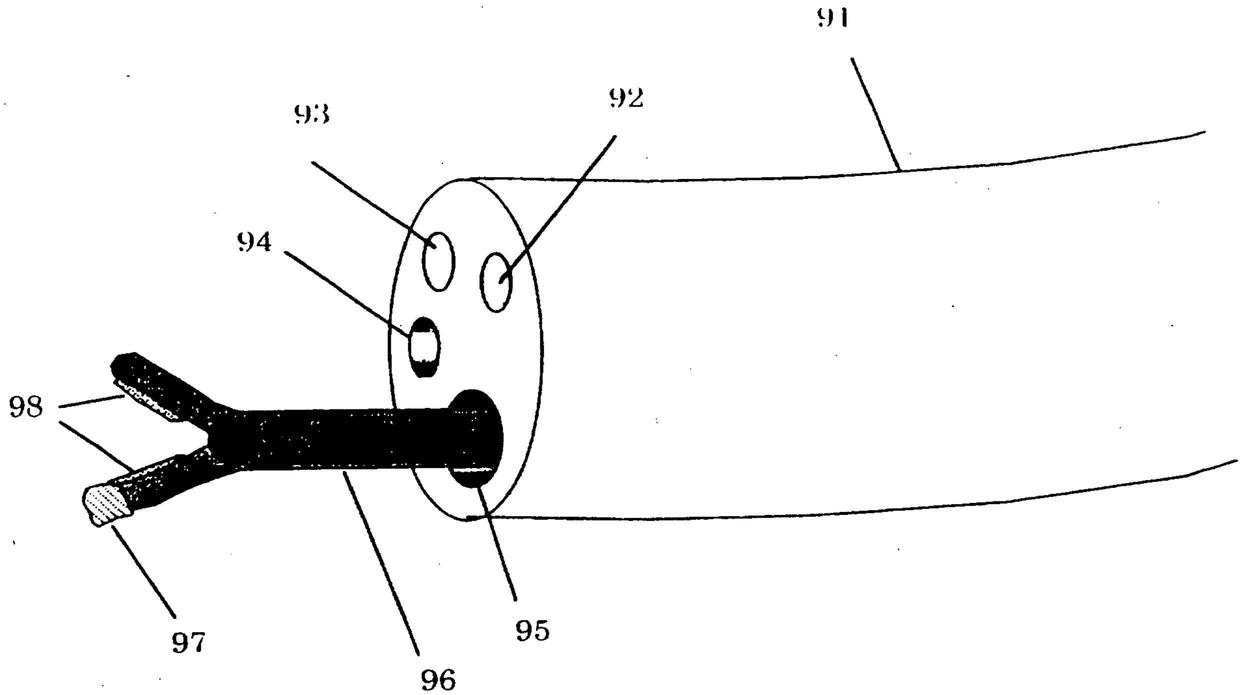
Figur 7



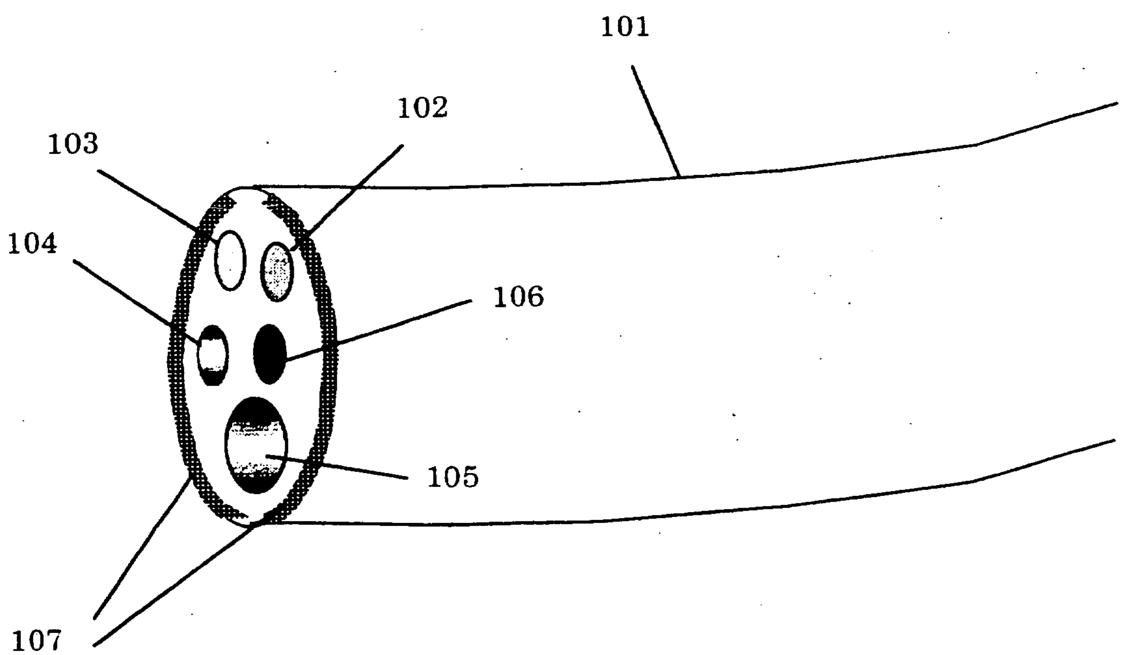
Figur 8 (a)



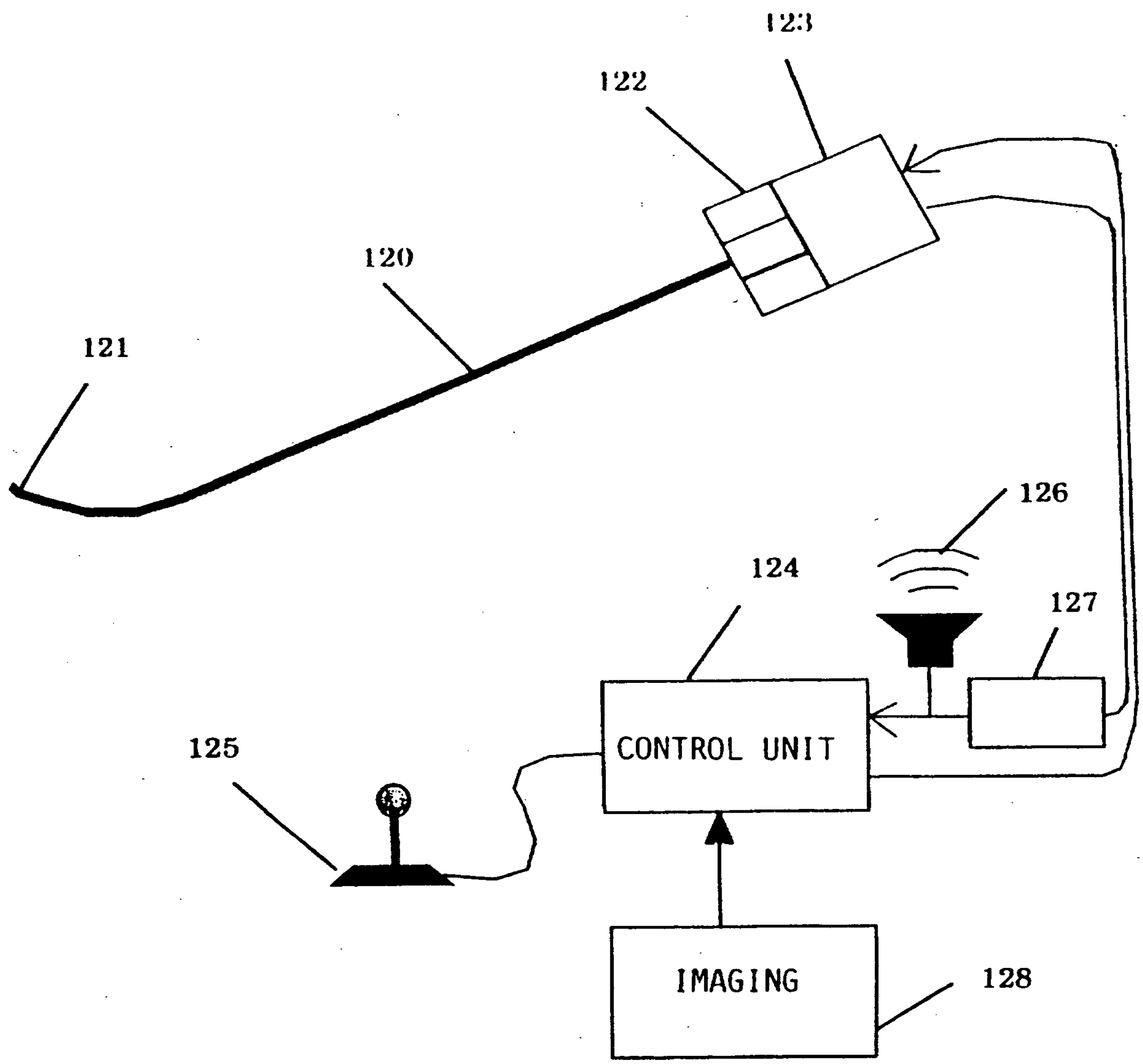
Figur 8 (b)



Figur 9



Figur 10



Figur 12

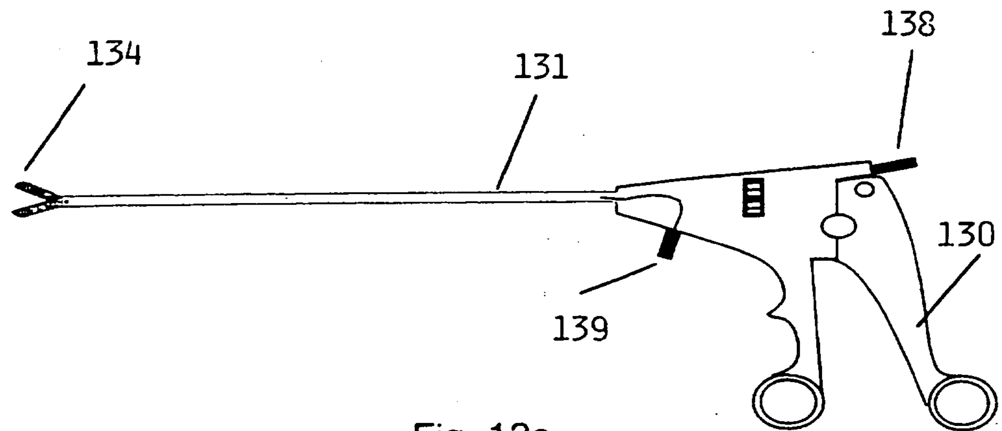


Fig. 13a

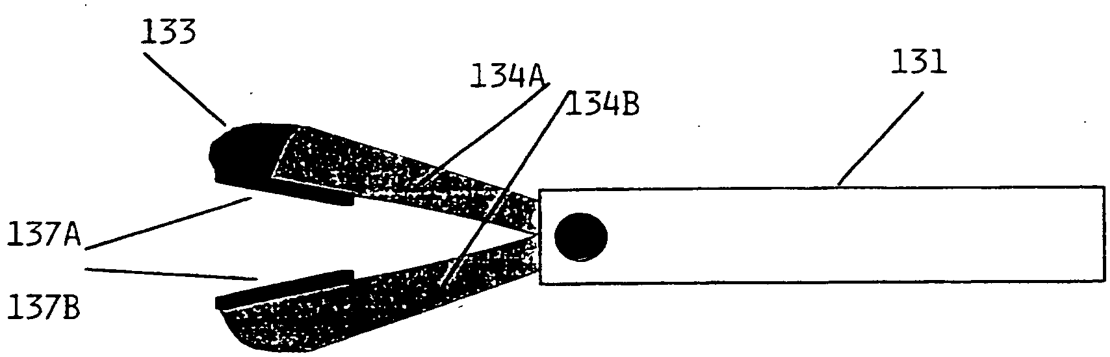


Fig. 13b

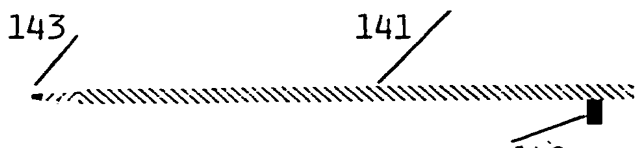


Fig. 14a

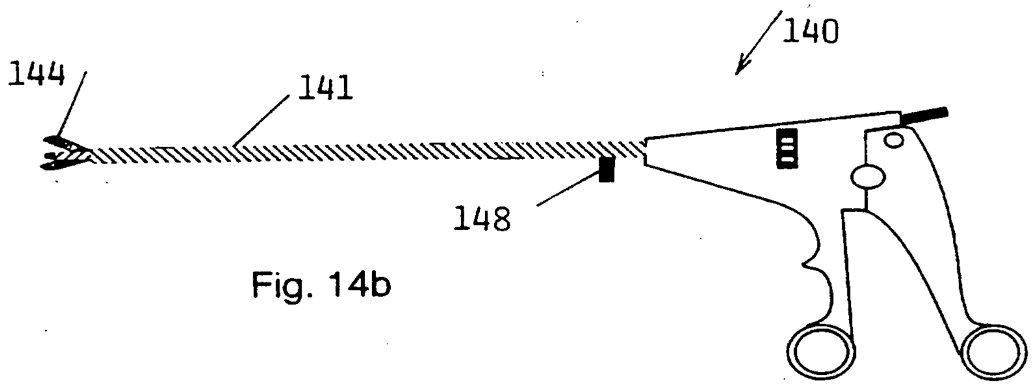


Fig. 14b

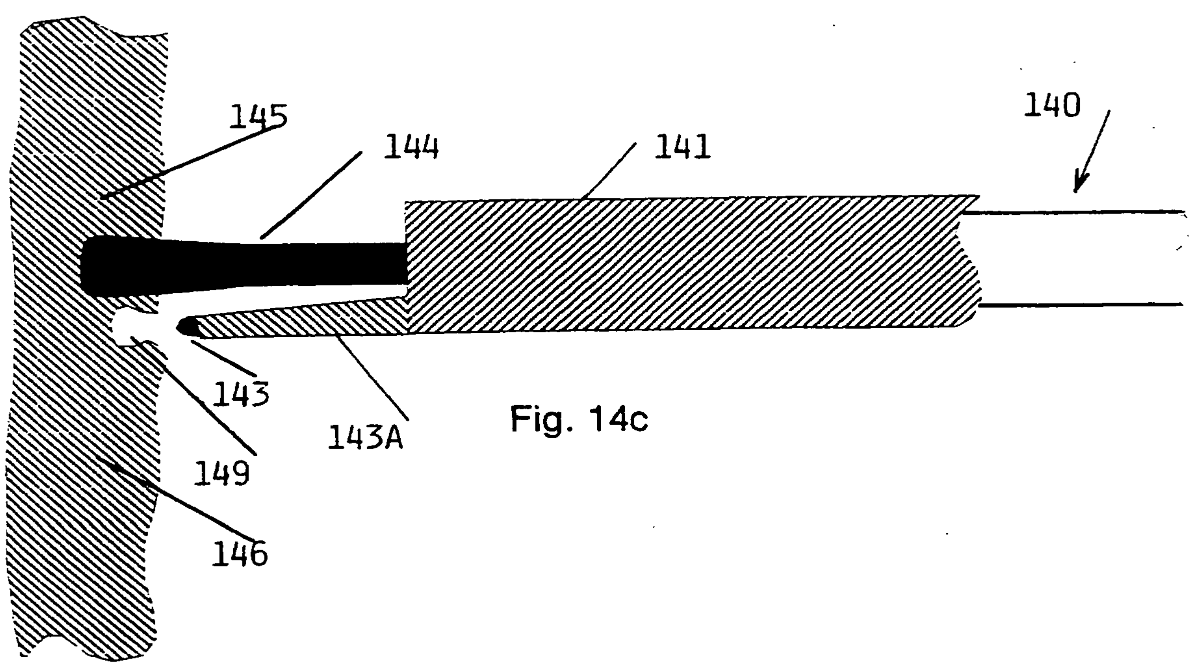


Fig. 14c

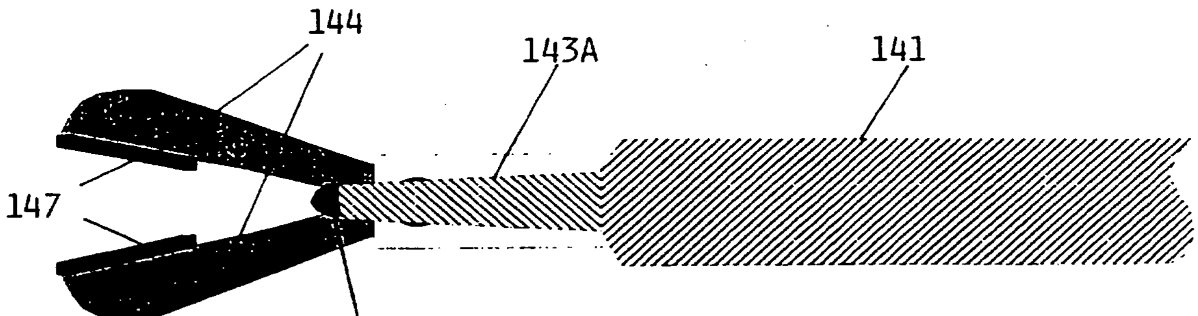


Fig. 14d

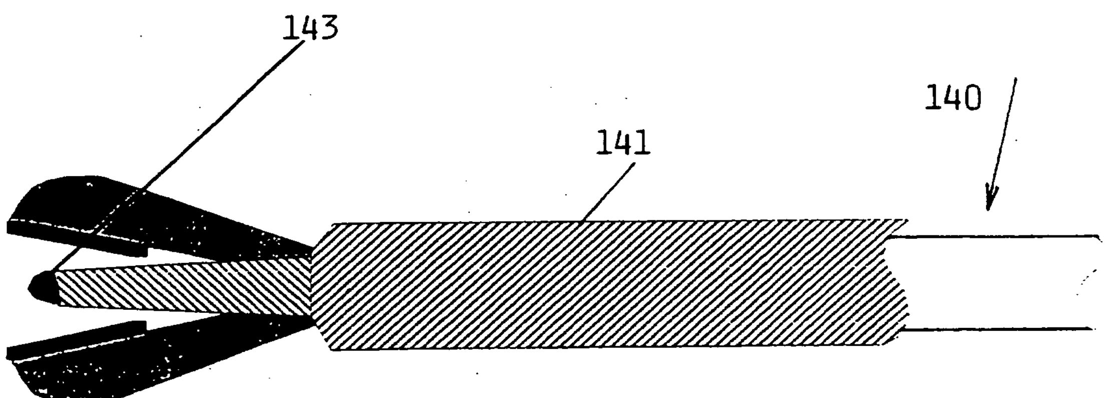


Fig. 14e

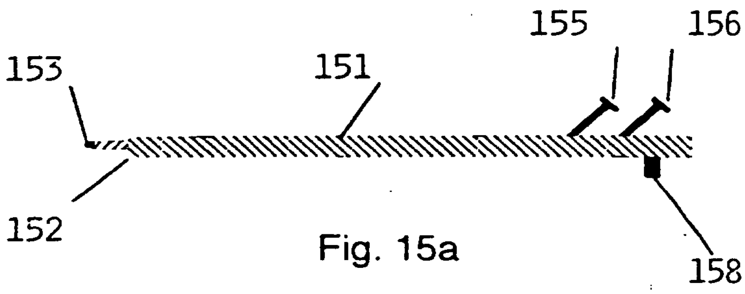


Fig. 15a

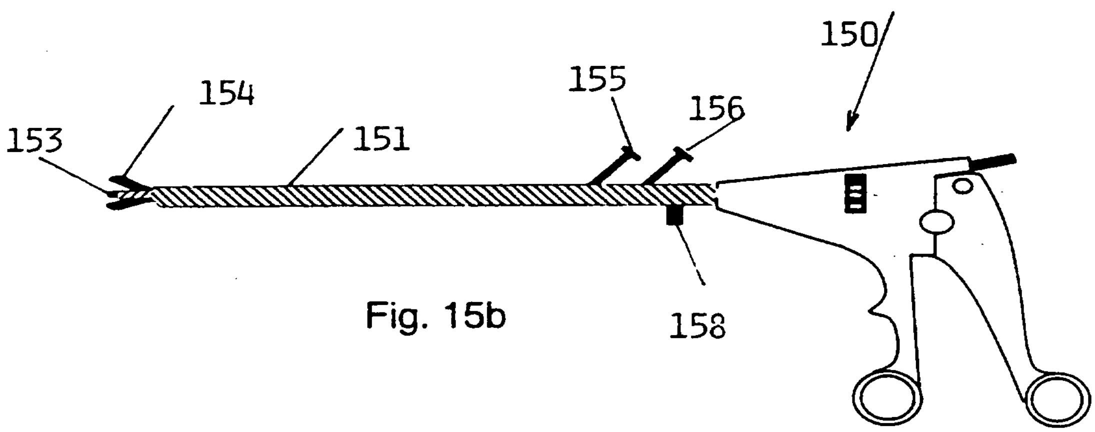


Fig. 15b

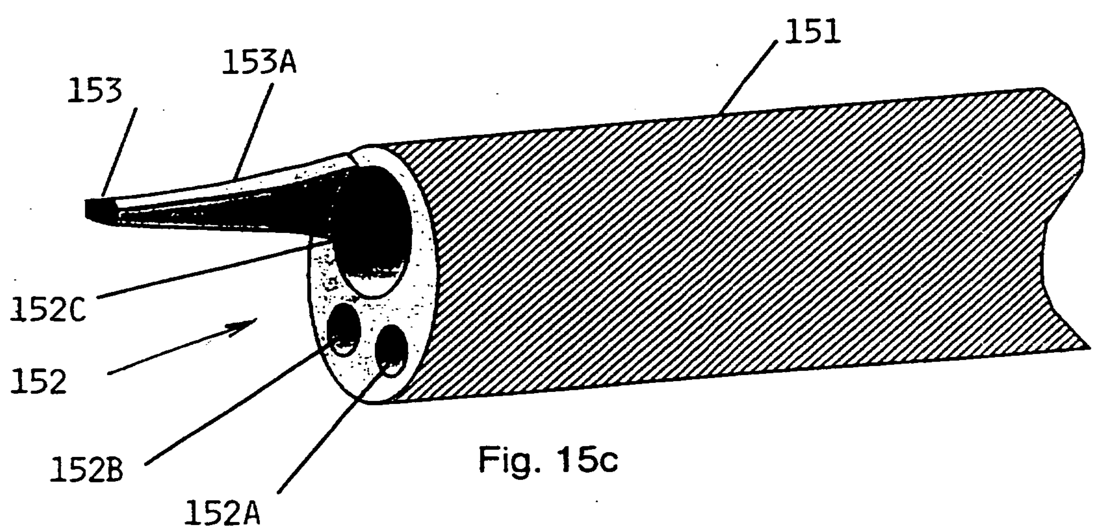


Fig. 15c

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 96/00263

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/02, A61B 17/36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5188111 A (DAVID C. YATES ET AL), 23 February 1993 (23.02.93) --	1-18
A	US 5376087 A (TERRY M. HABER ET AL), 27 December 1994 (27.12.94) -- --------	1-18

[ ] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" ertier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 March 1997	12.03.97

Name and mailing address of the ISA/	Authorized officer
Sw dish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Jack Hedlund Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

03/02/97

International application No.
PCT/NO 96/00263

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5188111	23/02/93	NONE	
US-A- 5376087	27/12/94	NONE	